UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

KIMBERLY C. CUTONE and ANTHONY CUTONE, Plaintiffs, v. ELI LILLY AND COMPANY, Defendant.	CIVIL ACTION No. 04-CV-12725 (JLT)

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR OPPOSITION TO DEFENDANT ELI LILLY'S MOTION FOR SUMMARY JUDGMENT

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I. INTRODUCTION

Diethylstilbestrol ("DES"), a mid-20th century fertility nostrum, has been banned by the Food and Drug Administration, recalled by the manufacturers and branded a carcinogen and teratogen by the World Health Organization, the National Institutes of Health (NIH), the American College of Obstetrics and Gynecology, and every health organization devoted to reproductive medicine. National Cancer Institute, National Institute of Child Health and Human Development & National Institutes of Health Booklet, Were You Born Between 1938 and 1971 Or Pregnant Then? If So, You Could Be Exposed To DES (Jan. 1995) (attached as App. 1); R.R. Greene, M.D., et al., Experimental Intersexuality: The Paradoxical Effects of Estrogens on the Sexual Development of the Female Rat, in The Anatomical Record 429 (Edward A. Boyden et al eds., 1939) (attached as App. 4). Even Defendant Eli Lilly and Company ("Defendant" or "Lilly") admits it was a mistake. See Lilly Research Laboratories et al, Withdrawal of Approval of 28 New Drug Applications (Food & Drug Admin., 65 Fed. Reg. 55,164-55165) (Sept. 13, 2000) (attached as App. 2).[1] The drug was sold to five to ten million women as a universal remedy to produce plump and healthy babies even though it never worked.[2] See W.J. Dieckmann, M.D., et al., Does the Administration of Diethylstilbestrol During Pregnancy Have Therapeutic Value?, 66 Amer. J. of Ob. & Gyn. 1062 (Howard C. Taylor et al eds., 1953) (attached as App. 5). Lilly failed to conduct a single test to investigate the effect of DES on the forming female daughter, even though it had known since the 1940's of reports in the literature

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1 See also CDC Resource Focuses on DES Exposure, 289 J. Amer. Med. Assn. 1624 (2003); Cynthia L. Orenberg, DES: The Complete Story (St. Martin's Press 1981); Barbara Seaman, The Greatest Experiment Ever Performed On Women (Hyperion Press 2003); Fenichell & Charfoos, Daughters At Risk: A Personal DES Story (Doubleday 1981)

2 In 1968, the National Academy of Sciences' review of the effectiveness of DES in preventing threatened or habitual abortion found that effectiveness cannot be demonstrated by the literature or its own experience. See Hearing Before the Subcomm. on Government Operations, 92nd Congress 77 (1971). At this time Lilly was asked by FDA to provide evidence that DES was effective and failed to provide any such information.

that estrogen and DES in high doses stunted the reproductive organs of the exposed daughter in animals. See Enders, Mink Production in Relation to Stilbestrol, in The Fur Journal, Sept.-Oct. 1950, at 4, 10 (attached as App. 3); App. 4.

The Defendant promoted DES for use by pregnant women, knowing it would affect the uterus of both the mother and daughter. They also knew the exposed daughter's uterus would not be put to the test or called into action for thirty-plus years. During that time, pharmacy records have been lost or destroyed and pharmacists have passed away, as has happened in this case. This is not the fault of Plaintiff Kimberly Cutone ("Ms. Cutone"), who was diligent, but the fault of the Defendant in placing an untested time bomb on the market with a forty-year fuse. Nonetheless, the Plaintiffs have gathered sufficient evidence to present a genuine issue of fact which warrants their day in court. Ms. Cutone's mother's clear identification of the unique signature features of the diethylstilbestrol pill she took, on top of a local pharmacist's testimony that Lilly was the only DES pill available in the region, together with proof of Lilly's dominance of the DES market in the late 1960's, provide enough evidence of product identification to allow a reasonable juror to conclude that it was more likely than not that Ms. Cutone was exposed to Lilly's DES. A Plaintiff in a civil case, unlike the government in a criminal case, has a much lower identification bar.

Ms. Cutone is entitled to stitch together eight facts thereby creating a quilt work which, in its totality, provides more than the minimum requirement of product identity:

1. Her mother, Virginia Camporesi, independently identifies the unique Lilly white cross-scored pill out of a photographic line-up.

2. Her mother's descriptions of the size, marking, and shape of the pill fits Lilly's DES tablet exclusively. No other manufacturer made a white, cross-scored, round DES tablet

without imprint besides Eli Lilly. Lilly's only alibi, the Bristol Myers Squibb DES, was a 100mg, cross-marked tablet with the word "Squibb" imprinted on one side of it. This does not match the pill the mother identified and disqualifies Squibb as a suspect.

3. A local pharmacist, Harold Sparr, testifies that the Lilly's DES was exclusively ubiquitous in the Boston Area in the late 1960's and early 1970's. (Affidavit of Harold B. Sparr, R.Ph., M.S. ("Sparr Aff."), attached as App. 7.)

4. The relevant wholesaler in the region and in this case was a Lilly wholesaler, under Lilly's control of the market, and was required to give priority to Lilly in filling an order for DES.

5. A national pharmacy expert and Lilly District Manager state the mother's description of the DES pill fits Lilly's only, and that the Lilly's DES constituted the lion's share of the Boston DES market.

6. Lilly admits it controlled the DES market.

7. Defendant Lilly, a multi-billion dollar company, with its thousands of pharmacy detailmen and voluminous records, has not come up with a shred of evidence that any other brand was available at the relevant pharmacy, or that any other brand made a small, round, white cross-scored DES tablet without imprint. In response to discovery, Defendant Lilly has no alibi. (See Def. Ans. to Int. ¶4, attached as App. 6.)

8. The 1969 Physician's Desk Reference ("PDR"), the authority on prescription medication for physicians, cited and indicated only Lilly's DES. (Attached as App. 21.)

II. PLAINTIFFS' RESPONSE TO DEFENDANT'S STATEMENT OF MATERIAL FACTS

1. Admitted.

2. Denied. Since the time of her answer to Defendant's Interrogatories, Plaintiff and her counsel, through discovery and investigation, have gathered various positive evidence from her mother's photographic identification, deposition testimony as well as the local pharmacist's testimony that Eli Lilly manufactured the DES pills that caused her reproductive injuries. (Tr. of Dep. of Virginia Camporesi ("Camporesi Dep.") at 47:7-15, 48:10-24, 45:14-20; 55:2-23, attached as App. 20; Report of Harold Sparr, R.Ph., M.S. ("Sparr Rep."), attached as App. 11; Sparr Aff.)

3-5. Admitted.

6. Denied. Mrs. Camporesi, who shopped at Bayard Pharmacy which was located in Boston, visually identified the white Lilly DES pill from a photographic lineup, which included various pills of different sizes and colors from a variety of brands. (Camporesi Dep at 47:7-48:24; photograph of Lilly DES pill, attached as App. 10). In addition, Lilly is, to a 99% degree of certainty, the only white cross-scored DES pill without any other markings available in Boston during 1969. (Sparr Rep. at 4; Sparr Aff. ¶8; Am. Statement of Philip J. Cafferty ("Cafferty Stmt.") at 5, attached as App. 22; App. 10.) Lilly cornered 94% of the DES market in Boston. (Sparr Rep. at 6; Report of Hannelore Vanderschmidt ("Vanderschmidt Rep.") at 4, attached as App. 22.) No other company had control of the DES market in the 1960's. (Cafferty Stmt. at 2-5.) Most other companies were only local and regional. For example, Person & Covey only sold DES to California, Arizona, and Nevada, but never in Massachusetts. (Dep. of Lorne Person, Sr. in Nierenberg v. Abbott Lab., No. 2958 (Pa. Ct. Com. Pl. 1993) (Apr. 22, 1994) at 122, attached as App. 13.)

7. Denied. There is no evidence that any of the sixty companies here manufactured them. Most companies listed in the Red and Blue Book in fact were not national manufacturers

or distributors as the Defendant implies – but instead were generic, local repackagers and bottlers. The great majority of the listings consist of local rebottlers who sold locally and regionally in limited areas of America and who manufactured nothing. See Sparr Aff. ¶11. The Red Book and Blue Book are technical catalogues of sellers and not accurate representations of the Boston or national DES market, nor do they supply any information as to what brand of DES was on the shelves of Bayard Pharmacy in 1969. (See Sparr Aff. ¶10; Sparr Rep.) It is inconceivable that any pharmacist would keep sixty brands of the same generic drug on their shelves. (In actuality, there were only six to eight name brand national manufacturers, not sixty as alleged by the Defendant. See Pls.' Counterstmt. of Facts in Issue ¶16).

8. Denied as prevarication. The Bristol-Myers Squibb DES pill, Stilbetin, had the emblem word "Squibb" imprinted on it. (Photograph of Squibb pill, attached as App. 8.) Mrs. Camporesi definitively testified that there were no markings aside from the cross-score on the diethylstilbestrol pill she took while she was pregnant with Ms. Cutone. (Camporesi Dep. at 55:6-12.) Squibb's Stilbetin, a pill that does not match the mother's descriptions, cannot exculpate Lilly.

9. Denied. There were no other name-brand, white, cross-scored diethylstilbestrol pill without writing aside from Eli Lilly's Diethylstilbestrol in the Boston region. (Sparr Rep. at 4; Sparr Aff. ¶8; Cafferty Stmt. at 5; App. 10.) A review of nearly 300 DES pill photographs of 100 different brands of DES collected since the 1980's yields no other DES pill with the same description. (Affidavit of Julie Zhang ("Zhang Aff."), attached as App. 9.)

10. Denied as prevarication. Mrs. Camporesi testified in her deposition that Dr. Philip McGovern, Sr., prescribed Diethylstilbestrol to her in order to treat symptoms of cramps, bleeding and to prevent a miscarriage. (Camporesi Dep. at 32:9-24, 37:2-7.) In addition, Dr.

Philip McGovern, Jr., the prescribing physician's son and his partner in practice in the 1960's and 1970's, testified that it was Dr. McGovern, Sr.'s usual and customary practice to prescribe DES to pregnant women who presented with indication for its usages, such as a history of threatened abortion. (Statement of Philip McGovern, Jr., M.D. ("McGovern Stmt.") at ¶4, attached as App. 14.)

11. Denied as prevarication. No one expects that the actual prescription would exist forty years later, but Mrs. Camporesi recalled and testified that Dr. McGovern, Sr. wrote Diethylstilbestrol on her prescription, which she then filled and took according to his direction in order to prevent miscarriage. (Camporesi Dep., 36:17-37:21.) In addition, the prescriber's then-partner, Dr. McGovern, Jr., testified that such a prescription for DES would have been the standard of care for Dr. McGovern, Sr. to treat the kinds of symptoms Mrs. Camporesi exhibited. (McGovern Stmt. at ¶4; Camporesi Dep., 32:9-24, 36:17-37:21.)

III. PLAINTIFFS' COUNTERSTATEMENT OF FACTS

12. Philip Cafferty, a Lilly Detailman and District Manager, testified that Lilly's DES was the only brand available in Massachusetts. (Cafferty Stmt. at 4-5.)

13. A local pharmacist who has worked in Suffolk County for the last fifty-six years and is familiar with the region where Plaintiff's mother purchased the DES in 1969 states that: "Lilly virtually owned that DES market" in the Boston area (Sparr Aff. ¶6), and "if a woman was dispensed DES as a white cross-scored tablet [in Boston] in 1969-1970, she would have received Lilly's Diethylstilbestrol..." (Sparr Aff. ¶8).

14. Lilly dominated the DES market in pregnancy sizes throughout the country and made a DES pill fitting the mother's descriptions. (Cafferty Stmt. at 2-5.) That is, Lilly is the only manufacturer that made a white, cross-scored tablet without imprint that was popularly used

to treat accidents of pregnancy in the 1960's. (Sparr Rep. at 4; Sparr Aff. ¶8; Cafferty Stmt. at 5; App. 10; Zhang Aff.) Most others were generic repackagers that distributed regionally. (Sparr Aff. ¶¶7, 9-11)

15. Lilly admitted that it sold DES in the relevant Boston region through the McKesson & Robbins wholesalers. (See Def.'s Resp. to Pls.' Interrogs. & First Req. for Produc. of Docs. and/or Tangible Things ("Def's Interrog. Resp.") No. 2, attached as App. 6.) James P. DellaVolpe, an employee of McKesson in the 1960's, testified that McKesson was a Lilly wholesaler, and by contract and agreement was required to supply only Lilly products on all unspecified DES orders, if Lilly made that product. (Statement of James P. DellaVolpe ("DellaVolpe Stmt.") at ¶6, attached as App. 26.) He further stated if a retail pharmacist ordered DES, McKesson would have filled the order with Lilly's DES and no other. (Id. at ¶¶7-8; Warehousing and Distribution Service Agreement, Eli Lilly and Company to Wholesalers (Jul. 1, 1970), attached as App. 15.)

16. Lilly admitted it held the lion's share of the DES market and produced 75% of the DES sold. Color Additives, Hearing on H.R. 7624 and S. 2497 Before the House Comm. on Interstate and Foreign Commerce, 86th Cong. 265, 277, 283 (1960) (statement of Thomas Carney, Vice President, Eli Lilly & Co.).

IV. DEFENDANT HAS NOT MET ITS SUMMARY JUDGMENT THRESHOLD

In order to prevail, Lilly must present to the court a scenario and setting which precludes the possibility that a reasonable juror could find in favor of the plaintiffs. The DES case of Shields v. Eli Lilly & Co., which centered on product identification, sets the bar:

> In a world short of absolutes, the jury is called upon to process less than perfect evidence. Litigants may not offer speculations or slight possibilities in support of their claims; but neither are they limited to offering only the incontrovertible. The

> jury's function contemplates that evidence may be less than indubitable.... Every conceivable alternative theory of causation need not be extirpated by a litigant seeking the jury's decision.

895 F.2d 1463, 1467 (D.C. Cir. 1990).

> Summary judgment should be granted only where the court, viewing the evidence in the light most favorable to the non-moving party, determines that no genuine dispute of material fact exists.... Facts are 'material' if they possess 'the capacity to sway the outcome of litigation under the applicable law.'

Great Northern Ins. Co. v. Paino Associates, 364 F.Supp.2d 7 (D.Mass. 2005).

> In examining the sufficiency of affidavits filed in connection with the motion, the affidavits of the moving party are strictly construed and those of his opponent liberally construed, and doubts as to the propriety of granting the motion should be resolved in favor of the party opposing the motion.

D'amico et al. v. Board of Medical Examiners et al., 520 P.2d 10 (CA 1974).

> The 'significantly probative' test does not require the nonmoving party to discredit every conceivable alternative theory of causation. As this court noted in Elliott v. Michael James, Inc., 507 F.2d 1179 (D.C. Cir. 1974), 'there is no requirement that the circumstances, to justify the inferences sought, negative every other positive or possible conclusion.' To be significantly probative, evidence need only be sufficient to permit a reasonable juror, indulging all reasonable inferences, to find that the party proved the element at issue....

Shields, 895 F.2d at 1465.

As a threshold requirement in a products liability case, identification of the injury-causing product must be established only by a preponderance of the evidence. Caldwell v. Fox, 231 N.W. 2d 46 (Mich. 1975). In the recent DES case of Dunseth v. Eli Lilly & Co., No. 03-CV-02123 (D.D.C. Mem. Op. Dec. 16, 2005) (attached as App. 17), Judge Walton, recognizing that summary judgment "is a drastic remedy, [and therefore] courts should grant it with caution so that no person will be deprived of his or her day in court to prove a disputed material factual issue," ruled that a plaintiff's mother's DES pill description, coupled with the affidavit of a local pharmacist (although not in the relevant store) identifying Lilly as the manufacturer of the drug

in question, created "an inference of probability" sufficient to defeat summary judgment. Dunseth at *3, *8 (quoting Zimmer v. Celotex Corp., 549 N.E.2d 881, 883 (Ill. App. Ct. 1989)).

Lilly, it seems, cannot take "no" for an answer. Less than six months ago, Judge Henry H. Kennedy denied Lilly's summary judgment attempt on product identification, stating: "The court is not only required to believe the competent evidence of the [Plaintiff], but must also grant all reasonable inferences in her favor." Gassman v. Eli Lilly & Co., No. 03-02592, mem. op. at *16 (D.D.C. Dec. 29, 2005) (attached as App. 18). On March 16, 2006, Judge Urbina again denied Lilly's summary judgment motion on product identification. Clayton v. Eli Lilly & Co., No. 04-1363, slip. op. (D.D.C. March 16, 2006) (attached as App. 19) ("In ruling on a motion for summary judgment, the court must draw all justifiable inferences in the nonmoving party's favor and accept the nonmoving party's evidence as true").

V. PLAINTIFFS PRESENT AMPLE EVIDENCE TO PROVE THAT LILLY'S DES WAS THE CULPRIT

In Kramer v. Weedhopper of Utah, Inc., 490 N.E.2d 104 (Ill. App. Ct. 1986), the court of appeals reversed the trial court's holding that 9-1 odds were not sufficient to create a fact issue as to identification. In Kramer, plaintiff was injured when his ultralight aircraft crashed. He sued the company that provided 90% of the bolts used to assemble the airplane. Specifically the appellate court said:

> the dispute centers on whether the fact that defendant supplied 90 percent of the bolts used by Weedhopper is sufficient circumstantial evidence to avoid entry of summary judgment. Circumstantial evidence consists of factors or circumstances which give rise to a reasonable inference of the truth of the underlying fact. The focus must then be on what quantum of evidence is sufficient for an inference to be reasonable. This measure has eluded specific standardization and enumeration. Generally the test of reasonableness resolves itself into a question of probability: is the inferred occurrence more probable than not, or is it merely possible. In the instant action there is evidence that
>
> 1) defendant supplied 90 percent of the relevant bolts

> 2) defendant supplied bolts to meet the general demand
> 3) other companies provided bolts only when necessary.
>
> Hughes Aviation was merely a 'possible source' and plaintiff need not, at summary decision, disprove that possibility. Defendant was allegedly the most probable cause of plaintiff's injury. The defects in plaintiff's proof are such that affect the weight, not whether there is a genuine matter triable question of fact.

Kramer, 490 N.E.2d at 107.

Drayton v. Jiffee Chemical Corp., 395 F. Supp. 108 (N.D. Ohio 1975), *aff'd* on issue of product identification, 591 F.2d 352 (6th Cir. 1978), highlights the importance of providing corroborative exclusion evidence. In that case, a minor plaintiff suffered severe burns from spilled liquid drain cleaner. The container was never recovered. However, plaintiff presented three witnesses to establish that the drain cleaner which caused plaintiff's injury bore defendant's label 'Liquid Plumr'. Id. at 356. Plaintiff's landlady testified that she had bought a bottle of 'Liquid Plumr' over one year prior to the accident, plaintiff's mother testified that she saw the bottle with the label 'Liquid Plumr' soon before the accident and plaintiff's father testified that he also saw the label prior to the accident. Defendant introduced expert testimony that both the use of the drain cleaner as described by plaintiff's father and the type of injury caused were consistent with a different drain cleaner. In finding that plaintiff's evidence was sufficient to establish product identification, the court looked at the totality of the evidence and held that for an inference to prevail that defendant's product was not involved, the court would have to find the unequivocal testimony of all plaintiff's witnesses to be incredible. That court, as this court should, was unwilling to make such a finding.

Finally, Liggons v. Roehm GMBH, 1993 US App Lexis 1335, *aff'd* (unpublished opinion) 983 F.2d 1067 (E.D. Mich 1993) reflects on statistical evidence and supports product identification with less than a 95% confidence level. In Liggons, plaintiff sued a handgun

manufacturer after she was struck by a bullet fired from a handgun that had fallen to the ground. One of plaintiff's experts testified, in part, that there were 83 derringers that possessed the same characteristics shown on the bullet, and 75 of those were manufactured by defendant. The court noted that although plaintiff had not established to a certainty that defendant had manufactured the handgun that caused the injury, they had produced sufficient evidence to raise a jury question. Id. at *1. The court commented that "plaintiff produced evidence 'tending to show' that defendants manufactured the gun in question." These authorities put the "blue bus" case cited by the Defendant at page 5 of their memorandum in its proper perspective.

A. Plaintiffs' Evidence Matches Lilly's DES Exclusively

Lilly's attempts to reduce and generalize Mrs. Camporesi's testimony to the blue bus case lacks accuracy and relevance.[3] See Def. Mem. at 5; Smith v. Rapid Transit, Inc., 58 N.E.2d 754-5 (Mass. 1945). It is uncontroverted that Ms. Cutone's mother was prescribed and ingested DES pills in order to prevent miscarriage while pregnant with Ms. Cutone in 1969-1970. (Camporesi Dep. at 32:1-24, 36:17-T37:21.) She recalls the pill she ingested was: (a) called Diethylstilbestrol (b) small, (c) round, (d) white, (e) with a cross on it, (f) given to prevent a miscarriage, and (g) had no other writing or markings on the pill. (Id. at 36:17-37:21; 45:14-20; 55:2-23.) Mrs. Camporesi visually identified and picked out the Lilly DES pill as the one she

[3] Even Professor Nesson, the creator of the Blue Bus hypothetical, explained: "At some point, high probability alone is sufficient to produce an acceptable verdict. In the blue bus hypothetical... evidence indicating a 55% likelihood that the plaintiff should recover presents a problem, whereas evidence indicating a 95% likelihood might not. Reaching a conclusion involves putting doubt aside. The difficulty of doing so will vary with the intensity of the doubt, the degree to which we are concerned about making a mistake, and the rationalizations we have to help us conclude." The Cutones, in this case, have cumulatively much higher than 95% of evidence identifying favor of the positive Lilly. Furthermore, Defendant regardless misuses the hypothetical in this setting. Professor Nesson emphasized: "Probability as we use the term in law, particularly in the civil standard of proof, is not a hard-edged mathematical concept. It is, rather, a concept that incorporates less rigid ideas of justice and reflects the judicial function of resolving disputes in the real world where values shift and knowledge is uncertain. An outcome is "probable" if it best accomplishes a just and acceptable resolution of the dispute. Probability as a legal concept in the law of proof, suggests wisdom, probity, and approbation—not favorable betting odds." Charles Nesson, Agent Orange Meets the Blue Bus: Factfinding at the Frontier of Knowledge, 66 B.U.L.Rev. 521, 522 n.3 (1986).

ingested from photographs of numerous different DES pills. (Id. at 47:7-15, 48:10-24.; App. 10 (photograph of identified pill).) Lilly's 25mg DES pill solely and exclusively fits those exact descriptions. (1969 PDR; App. 10.) In reality, Lilly's 25mg DES was the only DES product popularly available which was round, white, cross-scored, and without other markings. (Sparr Rep. at 4; Sparr Aff. ¶8; Cafferty Stmt. at 5.) No other commonplace DES therapy was available.

B. Squibb Is Not An Alternative

Lilly presents no evidence that Bayard's Pharmacy bought or stocked Squibb's DES pill, nor that anyone ever saw a Squibb DES product at the pharmacy. Most importantly, the Squibb pill is a non-alibi, because the mother's description of no markings other than the cross-score effectively rules out Stilbetin, which was imprinted with the "Squibb" emblem. (Camporesi Dep. at 55; see App. 8 (photo of Squibb pill, showing a faint "Squibb" imprint)).

The great majority of decisions on this point have repeatedly ruled that summary judgment is improper on product identification when a mother describes a white, cross-scored DES pill that resembled the Lilly DES. In Kogen v. Eli Lilly & Co., No. SACV 03-0962 (C.D.Cal. July 22, 2003), a mother remembered that she took a white, cross-scored pill for spotting but did not recall its name. Evidence was produced that the white-cross scored medicine was DES, and that Lilly made such a pill. With much weaker evidence than presented here, the court ruled that evidence was credible and sufficient to go to the jury and summary judgment was denied. Id. (attached as App. 23.)

In two other DES cases, district court judges have accepted the general "white cross-scored" description of the Lilly pill, the fact that the pill was taken to prevent a miscarriage, and evidence that Lilly's DES was routinely prescribed and dispensed in the area as sufficient triable

issues of fact to defeat summary judgment. Woolfolk v. Eli Lilly & Co., No. 2:03-cv-3577 (W.D.Wash., Mar. 15, 2005) (attached as App. 24); Brooks v. Eli Lilly & Co., No. 1:03-cv-1796 (D.D.C. July 28, 2005) (attached as App. 25).

Lilly is quick to point out its temporary victories in Bortell v. Eli Lilly & Co., No. 04-0954ESH, 2005 WL 3211719 (D.D.C. Oct. 20, 2005) (involving different issues of law on F.R.E. 807) and Galvin v. Eli Lilly & Co., No. 03-1797 (D.D.C. Sept. 12, 2005) (concerning Rule 56(e) affidavits issues), both currently pending in the Court of Appeals (which Lilly fails to advise the Court in its memorandum), but for the last twenty years they have been losing this point. Twenty years ago, the Seventh Circuit in McMahon v. Eli Lilly & Co., 774 F.2d 830 (7th Cir. 1985), gave Lilly the first of its many subsequent defeats. There, as here, the plaintiff was unable to provide the written prescription or any record of whose DES she was exposed to. Id. at 832. The manager of the relevant pharmacy could not remember any particular brand and could not negate Squibb or other brands. Id. Lilly presented two pharmacists who claimed that Squibb's and other brands were purchased by the pharmacy (something they have not ever tried in this case). Id. at 833-34. Both testified that Squibb's was cheaper and would have been used. Id. at 834.

In Gassman, this Court reaffirmed the McMahon decision and specifically ruled that the mother's description of the pill, along with a relevant pharmacist's testimony identifying Lilly as the exclusive DES dispensed, were sufficient to create a jury question and overcome summary judgment. No. 03-02592, mem. op. at *16.

C. The Recent DES Product Identification Decisions In Dunseth v Eli Lilly & Co. and Clayton v. Eli Lilly & Co. Set The Bar For DES Identification Evidence

In Dunseth, Defendant Lilly filed a motion for summary judgment on the same DES identification issue. (App. 17.) The plaintiff's mother in that case also recalled the description of the DES pill she took as white and cross-scored. A local Chicago-area pharmacist, Eugene Belczak, R.Ph. (who was not stationed at the relevant store), stated that the DES dispensed in that particular region could only have been Lilly's DES. The court denied Lilly's motion for summary judgment, stating:

> The Court finds that the description of the DES pills ingested by the plaintiff's mother, coupled with the affidavit of Eugene L. Belczak, create "an inference of probability" that the DES in question here was manufactured by the defendant.

Dunseth at 8. Like Mr. Belczak's affidavit in Dunseth, Pharmacist Sparr's affidavit, coupled with Plaintiff's mother's definitive description and identification of the Lilly's DES pill, should preclude summary judgment. The plaintiff in Dunseth had less of identification than Ms. Cutone, without a mother who had identified the Lilly pills from a photographic pill lineup, and still prevailed in summary judgment.

In Dunseth, as is here, Lilly's entire case is based on the Blue and Red Book. Id. at *2. Judge Walton, however, ruled that:

> this factual dispute is genuine because it is supported by admissible evidence—the likely testimony of Mr. Belcazk and the plaintiff's mother... Accordingly, this Court cannot conclude from the evidence before it that a reasonable juror could not find that the DES ingested by the plaintiff's mother was, in fact, manufactured by the defendant.

Id. at *9.

Similarly, in Clayton, the most recent federal court decision, Justice Urbina ruled that the reliability of a DES mother's visual identification of the DES pill from a photographic lineup

only goes to the weight of the evidence and is for a jury to decide. No. 04-1363, slip. op. at 7. The Zhang Affidavit, which is a review of nearly 300 DES pill photographs depicting 100 brands of DES that yielded no other pill matching the mother's description but Lilly's DES pill, was also taken into the court's consideration. Id.; see Zhang Aff. The court decided:

> Here, the plaintiff has met her burden because she submits evidence suggesting that: (1) the defendant is the only company that manufactured a 25 mg., white, cross-scored DES pill during the relevant time period and (2) the pharmacy where her mother filled her prescription dispensed the defendant's DES pills. The defendant, moreover, fails to point to any other manufacturers of 25 mg, white, cross-scored DES pills who sold their products in the Birmingham area. Accordingly, the court denies the defendant's motion for summary judgment.

Clayton at 9.

D. The Red and Blue Books Bear No Relevance To Any Material Facts In This Case

Pharmacist Sparr testified that in Boston during the 1960's to 1970's, pharmacies seldom bought generic drugs from the Red and Blue Book, as generics were unregulated, did not have the quality control of the major brands, and operated primarily in regional markets. (Sparr Aff. ¶P7, 9-11. See also Cafferty Stmt. at 3.) The Red and Blue Books are specialized pharmacological manuals and were offered in Defendant's motion without proper foundation or expert substantiation. There is no evidence that there were distributors, manufacturers, bottlers, labelers or middlemen. It is beyond the purview of this Court or the average juror to interpret their meaning and import without some expert pharmacy guidance as to what they mean. Availability, distribution, marketing, labeling are all unexplained. Nowhere do these publications set forth a national market. (See Sparr Aff. at 9-11.) For example, Person & Covey only sold DES to California, Arizona, and Nevada, but never in Boston. (Person Dep. at 122.) The Red and Blue Books provide no information that Person & Covey's or any other company's DES could be bought in Boston.

While the Red and Blue Books mean nothing to the average juror, the Physicians' Desk Reference is an accurate and well-known reference text on available drugs, which is sold in every bookstore. Lilly was the only DES manufacturer that maintained an advertisement in the 1969 PDR. (App. 21.)

E. Wholesaler DellaVolpe's Testimony Shows Lilly's Monopolistic Practices And Dominance In The Boston DES Market

Lilly had the lion's share of the relevant DES market through its rigorous promotion of DES and its monopolistic arrangement with drug wholesalers. (Cafferty Stmt. at ¶10; DellaVolpe Stmt. at ¶¶6-8.) Attached hereto as Appendix 15 is the Warehousing and Distribution Service Agreement that Lilly entered into with its wholesalers in the relevant time period, which was produced by Lilly in this case. In order to carry the Lilly line of drugs, Lilly required that wholesalers give "preference" to the Lilly product over all other competitors.

As the agreement reflects, a wholesaler had to agree to "not to...give preference to any other brand of products when no brand is specified" but rather to supply a Lilly product. (Lilly Distrib. Agmt. I(C).) This evinces custom and trade policy binding the wholesaler to supply a Lilly product over all competitors, virtually assuring that all DES in the Boston area was Lilly's DES.

McKesson and Robins Wholesale Company was the primary distribution center for pharmaceuticals in the Boston area in 1969. (DellaVolpe Stmt. at ¶2.) James P. DellaVolpe, an employee of McKesson and Robbins in the 1960's, testified:

> ...McKesson was a Lilly wholesaler. This meant that if a drug was ordered without a brand specification, that is ordered unspecified, a Lilly brand would have been supplied in furtherance of the agreement, which McKesson/Robbins had with the Lilly company. The ordinary routine and customary way of filling orders which were not specified by brand name would have been to ship a Lilly product, if they made it. Lilly made DES. When a retail pharmacist in the Boston

> area would have ordered DES, Diethylstilbestrol, or Stilbestrol, I would have gone to the Lilly section and filled the order with Lilly's brand of DES....

(Id. at ¶6.) In order to have the privilege of selling Lilly products, McKesson was required to sign the wholesale agreement with Lilly requiring them to ship Lilly exclusively in response to a "DES" or "Diethylstilbestrol" order. (Id. at ¶¶6-7.; Lilly Distrib. Agmt. I(C).) Lilly admits that McKesson was their wholesaler in the Boston region. (Def's Interrog. Resp. No. 2.). Mr. DellaVolpe attests to Lilly's dominance of the Boston DES market.

As a result, a reasonable juror could find that it is more likely than not that the Lilly brand of DES was all pervasive and ubiquitous in the drugstores of the Greater Boston area in 1969.

F. Harold Sparr, R. Ph. And Phillip J. Cafferty, R. Ph. Both Attest to Lilly's Dominance in the Boston DES Market. It is Factual and Scientific.

The Sparr survey study confirmed that Lilly possessed 94% of the DES market in 1969. (Sparr Rep. at 6.) That study meets criteria set forth in the Federal Judicial Center, "Reference Guide on Survey Research," Reference Manual on Scientific Evidence 229-271 (Fern M. Smith ed., 2d ed. 2000). It complies with all of the standards regarding design, administration and interpretation of a study to ensure objectivity, representative sampling and relevant population, and to avoid bias and protect from influence. The survey was designed by the Boston University and carried out by an uninterested and impartial pharmacy information process. (See Vanderschmidt Rep.)

Philip Cafferty began his pharmacy career in 1954, seven years before Ms. Cutone was exposed to DES. As a detailman for Lilly, he frequented doctors and drugstores to promote Lilly's products, all the while intermittently practicing retail pharmacy. Mr. Cafferty is supremely situated to address the practice of pharmacy over the last 50 years and the continuous

predominance of Lilly products in the 1950's through 1970's. Mr. Cafferty, with his experience in Indianapolis, the home of Lilly, and through the chain of marketing, promotion and delivery down to the 200 drugstores he physically observed in Boston and Rhode Island, was a unique expert in the field. He stated:

> Based upon my observations of drugstores and familiarity with the pharmaceutical field, Lilly had the lion's share, if not all of the DES market. I observed no other brand of DES in stores in Boston and Rhode Island in any meaningful quantity. With my experience and observations, it is inconceivable that I would not have seen it or heard of it, had it been there.

(Cafferty Stmt. at ¶16.)

G. Lilly Admits That It Held Preferential Position In The DES Market.

Even before the DES tragedy was in the media, Lilly's Vice President, Dr. Thomas Carney, testified before Congress that only three companies controlled the DES market and that Lilly had 75% of that market share:

> ...Mr. Mack: Doctor, is stilbestrol produced by most of the manufacturers, pharmaceutical manufacturers?
>
> Dr. Carney: No. I think stilbestrol is produced only by three companies in this country. Stilbestrol can be produced by anybody. It is an open compound.
>
> Mr. Mack: It is only produced by three manufacturers?
>
> Dr. Carney: Yes. As nearly as I know, three manufactures; yes, sir.
>
> Mr. Moss: What percentage of stilbestrol consumed in this country is produced by Eli Lilly?
>
> Dr. Carney: Maybe as high as 75 percent....

Hearing on H.R. 7624 and S. 2497 (statement of Thomas Carney).

VI. PLAINTIFF ANTHONY CUTONE HAS A VALID LOSS OF CONSORTIUM CLAIM

For reasons and evidence detailed above, there are genuine material facts in dispute on product identification such that a reasonable jury could find for the Plaintiffs. As such, Plaintiffs' ancillary claim for loss of consortium, which is a well-established cause of action in Massachusetts law, could prevail at trial and summary judgment ought to be denied. Olsen v. Bell Labs., Inc., 388 Mass. 171, 176 (1983); Diaz v. Eli Lilly & Co., 364 Mass. 153, 167-168 (1973).

VI. CONCLUSION

Summary judgment is provided to avoid wasting resources if a trial would be a waste of time. This court could avoid that contingency by bifurcating a trial requiring product identification to be adjudicated first. Perhaps a jury would not be convinced that it was more than likely a Lilly product. That would be a one-day trial. The Court could, if the evidence were so weak, then rule on the summary judgment or an N.O.V.

For the reasons set forth, Defendant Lilly's motion for summary judgment should be denied.

Respectfully submitted,

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Dated: May 25, 2006

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CERTIFICATE OF SERVICE

I, Erica Tennyson, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on May 25, 2006.

s/ Erica Tennyson
Erica Tennyson (BBO# 660707)